K014159

p1/2

JAN 18 2002

## 9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

1. The submitter of this premarket notification is:

Dave Osborn
Quality Program Manager
Philips Medical Systems
3000 Minuteman Road
Andover, MA 01810-1085

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This summary was prepared on 17 December, 2001

2. The names of these devices are:

- Philips M1175A/76A/77A Component Monitoring System
- Philips V24/V26 patient monitor

Classification names are as follows:

| Device Panel | Classification | ProCode | Description |
|---|---|---|---|
| **Panel 73 Anesthesiology** | 868.1400, II | CCK | Analyzer, Gas, Carbon-Dioxide, Gaseous-Phase |
| | 868.2375, II | BZQ | Monitor, Breathing Frequency |
| | 868.2480, II | LKD | Monitor, Carbon-Dioxide, Cutaneous |
| | 868.2500, II | KLK | Monitor, Oxygen, Cutaneous, for Infant not under Gas Anesthesia |
| **Panel 74 Cardiovascular** | 870.1025, III | DSI | Detector and Alarm, Arrhythmia |
| | 870.1025, III | MLD | Monitor, ST Segment with Alarm |
| | 870.1025, III | MHX | Monitor, Physiological, Patient (with arrhythmia Detection or alarms) |
| | 870.1100, II | DSJ | Alarm, Blood-Pressure |
| | 870.1110, II | DSK | Computer, Blood-Pressure |
| | 870.1130, II | DXN | System, Measurement, Blood-Pressure, Non-Invasive |
| | 870.1435, II | DXG | Computer, Diagnostic, Pre-Programmed, Single-Function |
| | 870.1915, II | KRB | Probe, Thermodilution |
| | 870.2060, II | DRQ | Amplifier and Signal Conditioner, Transducer Signal |
| | 870.2300, II | DRT | Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) |
| | 870.2340, II | DPS | Electrocardiograph |
| | 870.2340, II | MLC | Monitor, ST Segment |

| | | | |
|---|---|---|---|
| | 870.2370, II | KRC | Tester, Electrode, Surface, Electrocardiograph |
| | 870.2450, II | DXJ | Display, Cathode-Ray Tube, Medical |
| | 870.2600, I | DRJ | System, Signal Isolation |
| | 870.2700, II | DQA | Oximeter |
| | 870.2770, II | DSB | Plethysmograph, Impedance |
| | 870.2800, II | DSH | Recorder, Magnetic Tape, Medical |
| | 870.2810, I | DSF | Recorder, Paper Chart |
| | - | MSX | System, Network and Communication, Physiological Monitors |
| **Panel 80 General Hospital** | 880.2910, II | FLL | Thermometer, electronic, clinical |

3. The new devices are substantially equivalent to the previously cleared monitors in K003038, K001333, K990125, K981576, K971910, and K903771

4. The modification provides a choice of validation references, according to subclause 4.4.2.1 of AAMI SP-10 for pediatric and adult patients.

5. The new devices have the same intended use as the legally marketed predicate devices. They are intended for monitoring, recording, and alarming of multiple physiological parameters. For use in healthcare facilities by healthcare professionals whenever there is a need for monitoring the physiological parameters of adult, pediatric, or neonatal patients.

6. The new devices have the same technological characteristics as the legally marketed predicate devices.

7. Verification, validation, and testing activities established the performance, functionality, and reliability characteristics of the new device with respect to the predicates. Testing involved system level tests, integration tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate devices and test results showed substantial equivalence. The results demonstrate that modified devices meet all reliability requirements and performance claims.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 18 2002

Mr. Dave Osborn
Quality Program Manager
Philips Medical Systems
Cardiac and Monitoring Systems
3000 Minuteman Road
Andover, MA 01810-1099

Re: K014159
Trade Name: Philips M1175A/76A/77A Component Monitoring System and Philips V24/V26 Patient Monitor with M1008B and software release CMS C.1
Regulation Number: 21 CFR 870.1025
Regulation Name: Arrhythmia Detector and Alarm
Regulatory Class: Class III (three)
Product Code: DSI
Dated: December 17, 2001
Received: December 19, 2001

Dear Mr. Osborn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

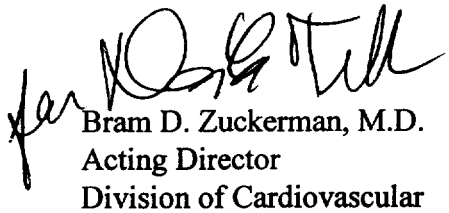
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K014159

Device Name: Philips M1175A/76A/77A Component Monitoring System and Philips V24/V26 patient monitor with M1008B and software release CMS C.1

Indications for Use: Intended for monitoring, recording, and alarming of multiple physiological parameters. For use in healthcare facilities by healthcare professionals whenever there is a need for monitoring the physiological parameters of adult, pediatric, or neonatal patients.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

**Concurrence of CDRH, Office of Device Evaluation (ODE)**

**Prescription Use** ✓ **OR** **Over-The-Counter Use**

**(Per 21 CFR 801.109)**

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K014159